

1 18. A method of claim 1, wherein said predetermined patterns outside the limbus of the cornea defined
2 by the area between two circles having radius of about 5.0 mm and 9.0 mm, respectively.

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4 19. A method of claim 1, wherein said predetermined pattern includes at least 3 radial lines around the
5 area outside the limbus.

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7 20. A method of claim 1, wherein said predetermined pattern includes at least two rings formed by 8
8 circular spots having a diameter of about (0.2 - 0.5) mm around the area outside the limbus.

9 21. A method of claim 1, wherein said sclera tissue is removed by said laser after the conjunctiva is open.

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11 22. A method of claim 1, wherein said sclera tissue is removed by said laser without opening the conjunctiva.
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21 **(II) Version with markings (underlines) to show changes made in SPECIFICATION and Claims:**

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23 **SPECIFICATION:**

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25 page 5: line 11 " pulse on corneal (changed to scleral) surface.... "

26 line 12 " on the corneal (changed to scleral) plane..... "

27 line 16 " scanned over the corneal (changed to scleral) surface "

28 page 6: line 13 " along the cornea (changed to sclera) radial direction "

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30 **CLAIMS:**

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32 1. A system (changed to method), adaptable for performing presbyopic correction in which a portion of the
33 corneal (deleted) sclera tissue is removed by steps of :

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35 (a) selecting a laser beam (deleted) having a predetermined wavelength ;

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37 (b) selecting a beam spot controller mechanism, said beam spot controller (deleted) to reduce and
38 focus said laser beam (deleted) to a fiber delivery unit;

39 (c) controlling the said fiber delivery unit to deliver said laser beam in a said (deleted)
40 predetermined pattern onto a plurality of positions on the corneal (changed to scleral) surface to remove
41 portion of the sclera tissue outside the limbus area, whereby a presbyopic patient's vision is corrected to
42 see near and far (deleted) by increasing the accommodation of the lens (changed to an eye).
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44 2. A system (changed to method) of claim 1, wherein said laser beam(deleted) is an ultraviolet laser having a
45 wavelength range of about (0.15 - 0.36) microns and a pulse duration less than about 200 nanoseconds
46 (corrected to nanoseconds.)
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- 1 3. A system (changed to method) of claim 1, wherein said laser beam(deleted) is an infrared laser having a
2 wavelength range of about (1.4 - 3.2) microns.
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- 4 4. A system (changed to method) of claim 2 (changed to 3), wherein infrared laser is an optically pumped
5 Erbium:YAG laser having a wavelength of about 2.9 microns.
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- 7 5. A system (changed to method) of claim 1, wherein said laser beam(deleted) is an ArF excimer laser
8 having a wavelength of 193 nm.
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- 10 6. A system (changed to method) of claim 1, wherein said laser beam(deleted) is a XeCl excimer laser
11 having a wavelength of 308 nm.
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- 13 7. A system (changed to method) of claim 1, wherein said laser beam(deleted) is a solid state diode laser
14 having a wavelength range of about (0.95 - 2.1) microns (add) with a power higher than 2 Watt (changed to
15 watts) and focused to a spot size less than 0.5 mm on the cornea (changed to sclera) surface.
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- 17 8. A system (changed to method) of claim 1, in which said beam spot controller consists of at least one
18 focusing spherical lens to couple the said laser beam to the said fiber delivery unit.
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- 20 9. A system (changed to method) of claim 1, wherein said fiber delivery unit consists of an optical fiber
21 having a length of about (0.5 - 1.5) meter and core diameter of about (0.2 - 0.8) mm and a hand piece
22 connected to a fiber tip.
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- 24 10. A system (changed to method) of claim 9, wherein said fiber delivery unit is substantially transparent to
25 the wavelength of the said laser beam.
26
- 27 11. A system (changed to method) of claim 9, wherein said fiber tip is made of a similar material as that of
28 the fiber and is made in one of the following shapes to focus the said laser beam onto the treated sclera area of
29 the eye: conical, spherical, 90-degree reflecting angle and flat end.
30
- 31 12. A system (changed to method) of claim 9, wherein said fiber tip focuses the said laser beam onto the
32 treated area of the eye at a spot size of about (0.1 - 0.5) mm in diameter.
33
- 34 13. A system (changed to method) of claim 9, wherein said fiber tip is made in a cylinder shape to focus the
35 said laser beam onto the treated area of the eye at a line shape having a dimension of about (0.1 - 0.4) in width
36 and (0.5 - 4.0) mm in length.
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- 38 14. A system (changed to method) of claim 9, wherein said fiber tip is operated in a contact-mode to ablate
39 the sclera tissue to a depth of about (300 - 800) microns.
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- 41 15. A system (changed to method) of claim 9, wherein said fiber tip is operated in a non-contact mode to
42 ablate the sclera tissue to a depth of about (300 - 800) microns.
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- 44 16. A system (changed to method) of claim 1, wherein said fiber delivery unit is controlled by the surgeon to
45 perform a predetermined patterns outside the limbus of the cornea by manually moving the fiber tip in the
46 radial direction of the cornea.
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- 48 17. A system (changed to method) of claim 1, wherein said fiber delivery unit is attached to a scanning device
49 to perform said predetermined patterns outside the limbus of the cornea and scan said laser beam along the
50 radial direction of the cornea.
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- 52 18. A system (changed to method) of claim 1, wherein said predetermined patterns outside the limbus of the
53 cornea defined by the area between two circles having radius of about 5.0 mm and 9.0 mm, respectively.
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1 19. A system (changed to method) of claim 1, wherein said predetermined pattern includes at least 3 radial
2 lines around the area outside the corneal (deleted) limbus.

3
4 20. A system (changed to method) of claim 1, wherein said predetermined pattern includes at least two
5 rings formed by 8 circular spots having a diameter of about (0.2 - 0.5) mm around the area outside the
6 corneal(deleted) limbus.

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8 21. A method of claim 1, wherein said sclera tissue is removed by said laser beam(deleted) after the cornea
9 (deleted) conjunctiva is open.

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11 22. A method of claim 1, wherein said sclera tissue is removed by said laser beam(deleted) without opening
12 the cornea(deleted) conjunctiva.

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21 (III) REMARKS:

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23 1. Comments on prior art of Schachar US Pat #5,489,299 (Schachar, 299) which has the following
24 Claims:

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26 1.1 Claims 1 and 29, the basic theory in Schachar "299, requires the increase of the radial distance
27 (referred as D) between the equator of the crystalline lens and the inner diameter of the ciliary
28 muscle. This distance (D) was actually decreased rather than increased during accommodation
29 according to the published results of Glasser et al in: (a) Ophthalmology 1999, Vol. 106, pp. 863-
30 872, pp.873-877; (b) Ophthalmology, vol. 108, pp. 1544-1551, 2001; (c) EyeWorld, (Sept, 2001),
31 pp.26-29; p. 32. Therefore, Schachar'299 based on the increasing of D for accommodation could be
32 totally wrong. The present application of Lin for accommodation is based on the classical theory of
33 Helmholtz which is opposite to Schachar's theory. The Claim 1 of the present application of Lin
34 does not require the increase of D as required by Schachar' 299 Claim 1.

35 1.2 Claim 34 of Schachar '299 proposed to use the method of claim 29 by applying heat to adjacent
36 tissue within the eye. Claim 35, 36 and 37 proposed the use of lasers to create this thermal effect to
37 reposition the insertion stated in claim 29. Claim 39 essentially proposed virtually all possible
38 lasers which most are thermal lasers and few of are cold lasers.

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40 1.3 In lines 53 - 59 of column 7 of Schachar'299, he proposed using laser for ablating the scleral
41 surface based on the concept of "weakening and expanding" the sclera. This concept was reported
42 to be wrong (per above discussion in 1.1). Schachar did not present any details or practical methods
43 for ablating the scleral. In fact, this ablating laser proposed in col. 7 is in conflict with the thermal
44 lasers proposed in his Claims 34 - 39. Moreover, this prior art did not teach any of the clinically
45 important issues which are essential for efficient presbyopia corrections and proposed by the present
46 application of Lin): depth, length, pattern and location of the laser ablation area and the
47 treatment of the conjunctival layer before the ablation of the underneath sclera.

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50 1.4 In lines 10-20, Col. 8 of Schachar'299, he proposed a laser to excise a small strip of sclera and
51 replaced by an alloplant (which is not required by the present application of Lin); He also proposed
52 a laser to decompose the collagen fiber (which is totally different from what was proposed by the
53 present application of Lin).

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3 1.4 The teachings proposed in claims 29 – 37 of Schachar using a thermal laser for presbyopia treatment
4 will cause the following clinical problems: myopic shift of the cornea due to the thermal shrinkage
5 caused by laser heating, thermal damage of the scleral and ciliary body, and tissue healing effects
6 after the treatment which will show a huge regression.
7

8 To summarize, Schachar's teachings in his '299 patent (using laser heating effects) will not provide
9 efficacy or safe treatment for presbyopia other than causing the thermal damage on the eye and the
10 myopic shift of the cornea. The theory he proposed in the '299 patent is not consistent with others. The
11 theory proposed by the present application is based on "cold lasers" for efficient tissue ablation without
12 thermal damage to the eye or cause the cornea to change its shape such that patient's far vision remains
13 after the treatment. Greater detail about the present application is described as follows.
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16 **2. The following new features and teachings of the present application n. 09/706,382 (Lin'382) are**
17 **not presented and cannot be achieved by prior art Schachar '299:**
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19 2.1 Claim 1 of Lin'382, proposed laser with predetermined wavelength (such that only ablative lasers can
20 be used); a fiber delivery unit (such that laser energy can be delivered to the predetermined area
21 without using a scanning device); ablation area is outside the limbus (such that the cornea curvature
22 and patient's far vision is not affected); patient's near vision is corrected by accommodation
23 increasing (which did not require the increase of radial distance by sclera radial expansion proposed
24 by Schachar'299).

25 2.2 Specific parameters proposed in Claims 2-20 of Lin'382 are not mentioned at all in Schachar's'299,
26 these parameters are clinically important for presbyopia correction, including the selected "ablative-
27 type" laser wavelength, coupling to a fiber, fiber structures and its operation modes, patterns of
28 ablation.

29 2.3 Claim 12, with laser spot size of 0.1 – 0.5 mm are required for accuracy and high laser fluency for
30 effective ablation. Laser with larger spot sizes and/or lower fluency will cause thermal effects and
31 cornea shrinkage rather than ablation.

32 2.4 Claims 21 and 22 proposing two methods for removing the sclera, with or without opening the
33 conjunctival layer.
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35 The proposed parameters in Lin'382 are clinically important for effective increase of the sclera elasticity for
36 accommodation whereas keeping the cornea center area intact to avoid hyperopic or myopic shift, which
37 occurred in the radial keratotomy (RK) procedure when the incision was done inside the limbus to correct
38 myopia. Therefore, the proposed method of presbyopia correction requires both a cold laser for minimum
39 thermal shrinkage of the cornea and ablating areas outside the limbus to avoid cornea shaping. Lack of either
40 condition will cause cornea damage and poor efficacy of accommodation.
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44 **3. Comments on the prior arts of US Pat.5,520,679 (Lin'679) and others.**
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46 The prior art of Lin'679 is dealing with laser ablation in the central portion of the cornea to reshape its
47 curvature and it is limited to myopia or hyperopic corrections, not for presbyopia correction (which require the
48 change of the sclera tissue properties). The present Lin'382 application, on the other hand, is dealing with
49 sclera tissue outside the limbus to avoid the cornea reshaping. Therefore Lin' -382 and Lin'679 are a totally
50 different procedures and based on fundamentally different concepts. None of the teachings in Lin'679 can be
51 used for the proposed new procedure in Lin'382 without realize the clinically important issues of presbyopia
52 which require different ablation patterns, location and mechanisms.

1 The teachings in prior arts of Rozoius (5741247), Tsushima (5845024) and Mathis (5599342) using XeCl
2 laser and fibers for other procedures, are therefore not obvious, since the present Lin'382 application are
3 technically and clinically different from prior arts of Lin'679 and Schachar'299.

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5 **4. Comments on the 'Double patenting'.**

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7 The present application Lin'382 have the following important features (Claims) than the prior US
8 patent No. 6,258,082 (Lin'082) and no. 6,263,879 (Lin'879):
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- 10 4.1 Claim 1 of Lin'082 and Claim 3 of Lin'879 proposed a "scanning mechanism" and they are limited
11 to this "narrow" claim, in which the scanning device has disadvantages over the "fiber delivery"
12 proposed in Claim 1 of Lin'382 (the present application). See lines 9-22 on page 3 of Lin'382.
13 4.2 Claim 1 of Lin'382, specifically claims on using a fiber to generate the predetermined patterns
14 which can not be achieved by prior arts of Lin'082 or Lin'879.
15 4.3 Claims 8-17 of Lin'382 are not covered by prior arts of Lin'082 or Lin'879 and these features/Claims
16 are clinically important.
17 4.4 Claims 21 and 22 of Lin'382 are also new concepts not covered by Lin'082 or Lin'879.
18 4.5 Claim 1 of Lin'879 using the concept of sclera expansion for accommodation whereas Lin'382 did
19 not require an "expansion", but only required the change of the sclera tissue property (see lines 6-8 of
20 page 2 in the specification).
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23 In view of above discussions, the present inventor believes that Lin'382 application should not be subject
24 to the "double patenting rejection". And we would like to consider : a) removing some Claims in this
25 application which may overlap with the Claims of Lin'082 or Lin'879, or b) file a "Terminal Disclaimer",
26 or c) doing both.
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